FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Antiviral Drugs Advisory Committee (AVDAC)
Hilton Hotel, Washington DC/Silver Spring
8727 Colesville Road, Silver Spring, MD
June 2, 2010
AGENDA

The committee will discuss biologics license application (BLA) 125283, motavizumab, single-dose liquid solution 50 mg/0.5 milliliter (mL) and 100 mg/1 mL vials, MedImmune, LLC, for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease.

8:00 a.m. – 8:10 a.m.	Call to Order Introduction of Committee	**Craig W. Hendrix, M.D.** Acting Chair AVDAC
8:10 a.m. – 8:15 a.m.	Conflict of Interest Statement	**Paul T. Tran, R.Ph.** Designated Federal Official, AVDAC
8:15 a.m. – 8:30 a.m.	FDA Opening Remarks	**Debra B. Birnkrant, M.D.** Director Division of Antiviral Drug Products (DAVP) Office of New Drugs (OND), CDER, FDA
8:30 a.m. – 10:00 a.m.	**Applicant Presentation**	**MedImmune, LLC**
	Regulatory Affairs, Introduction	**Ross Lobell** MedImmune
	RSV Overview	**Octavio Ramilo, M.D.** Nationwide Children's Hospital
	Clinical Development, Efficacy	**Pamela Griffin, M.D.** MedImmune
	Clinical Development, Safety	**Genevieve Losonsky, M.D.** MedImmune
	Risk Assessment	**Mark Boguniewicz, M.D.** Immunology Professor National Jewish Health University of Colorado Denver School of Medicine
	Benefit Assessment	**Octavio Ramilo, M.D.** Nationwide Children's Hospital

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	Clinical Development, Post Approval Commitments	**Gregory Geba, M.D., M.P.H.** MedImmune
10:00 a.m. – 10:15 a.m.	Clarifying Questions to Applicant	
10:15 a.m. – 10:30 a.m.	**Break**	
10:30 a.m. – 11:15 a.m.	**FDA Presentation**	**Alan Shapiro, M.D., Ph.D.** Medical Officer DAVP, OND, CDER, FDA
11:15 a.m. – 12:00 p.m.	Clarifying Questions for FDA and Applicant	
12:00 p.m. – 1:00 p.m.	**Lunch**	
1:00 p.m. – 2:00 p.m.	Open Public Hearing Session	
2:00 p.m. – 2:15 p.m.	Charge to the Committee	**Debra B. Birnkrant, M.D.**
2:15 p.m. – 4:00 p.m.	Questions for Discussions	
5:00 p.m.	**Adjournment**	